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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/992,132	11/15/2001	William K. Summers	30011-U.1	4628

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EXAMINER
COE, SUSAN D

ART UNIT	PAPER NUMBER
2654	7

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/992,132	SUMMERS, WILLIAM K.
Examiner	**Art Unit**
Susan Coe	1654

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *3,6-8,15-20 and 22-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,9-14 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 and 4*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed November 25, 2002 has been received and entered.

2. Claims 1-33 are currently pending.

Election/Restrictions

3. Applicant's election of phosphatidylcholine for species A and the composition of claim 13 for species B in Paper No. 6, dated November 25, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 3, 6-8, 15-20 and 22-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

5. Claims 1, 2, 4, 5, 9-14, and 21 are examined on the merits.

Claim Objections

6. Claims 2 and 13 are objected to because of the following informalities: in claim 2, line 2, "phosphatidylcholine" is misspelled as "phoshatidylcholine." In claim 13, line 8, "ginkgo" is misspelled as "ginko." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 5, 9-11, 13, 14,and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,043,323.

US '323 teaches compositions contains phosphatidylcholine, bioflavanoids, ginkgo biloba, and or quercetin (see claims). The ingredients can be present in a variety of amounts (see Examples). The composition can be administered orally, rectally, or topically (see column 5, lines 30-35 and 42).

US '323 does not specifically state that the bioflavanoids or the quercetin come from the plant sources claimed; however, these compounds would be the same compounds regardless of the source of the compound. Therefore, the bioflavanoids and quercetin taught by US '323 is considered to be the same as that claimed by applicant. In addition, the reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

8. Claims 1, 2, 4, 5, 9-14 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,648,377.

US '377 teaches a composition of 80 mg of proanthocyanidins and 100 mg of phosphatidylcholine. The composition is administered orally (see Example III).

US '377 does not specifically state that the proanthocyandins come from the plant sources claimed; however, these compounds would be the same compounds regardless of the source of the compound. Therefore, the proanthocyanidins taught by US '377 are considered to

be the same as that claimed by applicant. The reference also does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 2, 4, 5, 9-14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,043,323, US Pat. No. 5,648,377, and Castleman (*The Healing Herbs* (1991), Rodale Press: Pennsylvania; Barberry, pp. 59-61; Ginseng, pp. 193-200; Gotu Kola, pp. 205-208; and Turmeric, pp. 355-357).

US '323 teaches compositions contains phosphatidylcholine, bioflavanoids, ginkgo biloba, and/or quercetin (see claims). The ingredients can be present in a variety of amounts (see Examples). The composition can be administered orally, rectally, or topically (see column 5, lines 30-35 and 42). The composition has antihypertensive and antiinflammatory effects (see Tables 1 and 2).

US '377 teaches a composition of 80 mg of proanthocyanidins and 100 mg of phosphatidylcholine. The composition is administered orally (see Example III). The composition has antiinflammatory and antiatherosclerotic properties (see claim 9).

Castleman teaches that barberry has antihypertensive and antiinflammatory properties (see page 60). This reference also teaches that ginseng and Siberian ginseng have antiatherosclerotic properties (see page 193 and 196). Castleman also teaches that gotu kola stimulates circulation (see page 206). In addition, the reference teaches that curcuma has antiatherosclerotic properties (see page 356).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that treat conditions that cause heart disease. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to treat conditions that cause heart disease, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat conditions that cause heart disease. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are

no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The references also do not specifically teach administering the composition in all of the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the references in the forms claimed by applicant.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The

examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
December 19, 2002

LEON B. LANKFORD, JR.
PRIMARY EXAMINER